K091803

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OCT - 9 2009

6 July 2009

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) Refer to information above and concluding this summary.

(a)(2) Name of the Device

Model Number / Name:	**SmartTrack System**
Classification Name:	Nebulizer (Direct Patient Interface)
	Anesthesiology Devices, 21 CFR §868.5630, Class II, CAF

(a)(3) Identification of Legally Marketed Devices

K990185	MDILog Model MDC-512	Medtrac Technologies Inc
K970344	MDILog Model MDC-511	Medtrac Technologies Inc
K935955	Doser MDI Counter	Newmed Corporation

(a)(4) Description of the Device

The SmartTrack System consists of three modules used to provide a compliance monitoring function for use of a Metered Dose Inhaler (MDI).

- **SmartTrack** is a clip-on module that attaches externally around the enclosure of an MDI, using an optical sensor to detect MDI actuation, to log the usage history of the MDI. The device includes an LCD display and control buttons to review basic data and adjust device settings. Various device status conditions are indicated to the user, and logged to provide potentially relevant context for later review of MDI usage history data.

- **SmartTrack Docking Station** is an optical interface cradle used to download data stored on the SmartTrack module, via USB cable connection to a PC, and allow for interaction by the offline software with device settings and status monitoring.

- **Respiratory Analyzer** is a software application for use on a PC that provides for offline review of the MDI compliance data logged by the SmartTrack module. Data is stored in database files with patient, medication, and prescribed dose information, and is available for review and export in various table and graph formats to highlight MDI usage characteristics.

(a)(5) Statement of the Intended Use

The SmartTrack System is intended for single-patient use as an electronic data capture accessory for recording and monitoring actuations of prescribed MDI usage. This may be used in the following applications:

- In clinical trials, where researchers need to know when a patient has actuated their trial MDI medication;
- In clinical practice, where specialists, general practitioners, and nurse educators need to know if a patient has actuated their prescribed MDI medication.

The SmartTrack is not intended to indicate remaining quantity of medication in an MDI and does not include a dose counting function.

(a)(6) Technological Characteristics Summary

Technological characteristics of the SmartTrack system are largely equivalent to the predicate devices listed above. Equivalent features between the devices include: configuration in attaching to the outside of an MDI enclosure; microprocessor control and use of an internal clock, to log date and time of MDI actuations; power supply from an internal battery; interface to a personal computer via an optical docking station to download MDI usage data; and offline review software providing for data handling, device interaction, and patient data reporting functions.

The sensor technology used to detect MDI actuation is different from the predicate devices, and this aspect of the device has been verified by non-clinical testing to establish equivalent performance to the predicate devices.

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the SmartTrack system has been carried out to cover functional verification and device performance. This included completion of software verification procedures, with performance testing of the MDI actuation sensor system to ensure data is logged accurately for MDI usage. This established correct functionality of the SmartTrack System according to requirements.

Third party testing of the SmartTrack System for compliance to IEC 60601 series standards for general safety and electromagnetic compatibility, and IEC 60068 series standards for environmental testing, will be completed by an accredited laboratory before marketing of the device.

(b)(2) Discussion of the Clinical Tests

Clinical testing was not required to demonstrate the safety and effectiveness of the SmartTrack System. The product functionality has been adequately assessed by bench testing as above.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

Hardware testing carried out for the SmartTrack System indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and the system configuration functions equivalently to the predicate devices. The device will meet standard requirements for electrical safety and electromagnetic compatibility before marketing.

This information indicates that the SmartTrack System is equivalent to the predicate devices in terms of device safety and effectiveness.

Garth Sutherland
Chief Operating Officer
Nexus6 Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Nexus6 Limited
C/O Mr. Morten Simon Christensen
Responsible Third Party Official
Underwriters Laboratories, Incorporated
455 East Trimble Road
San Jose, California 95131-1230

OCT – 9 2009

Re: K091803
Trade/Device Name: SmartTrack System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: September 22, 2009
Received: September 24, 2009

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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9 October 2009

INDICATIONS FOR USE

510(k) Number: K091803

Device Name: SmartTrack System

Indications for Use:

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Prescription Use ✓ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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